APR 1 3 2012

K120315

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510(k) Summary: *syngo*.MR Spectroscopy

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

Date of Summary Preparation: January 30, 2012

1. General Information:

Importer/Distributor
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2. Contact Person

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3. Device Name and Classification

Data	Details
Trade name / Device Proprietary Name:	*syngo.MR* Spectroscopy. Please note: *syngo.MR* Spectroscopy is also known as *syngo.MR* Spectro Engine which is the commonly used trade name for *syngo.MR* Spectroscopy
Classification Name:	Regulation Description:

Data	Details
	- Picture Archiving and Communication System (PACS)
Classification Panel:	Radiology
Device Classification:	Class II devices
Regulation number:	21 CFR 892.2050
Product Code:	LLZ, LNH

4. Device Description

syngo.MR Spectroscopy is a *syngo*.via-based MR spectroscopy data viewing, processing and reading software. This software allows MR spectroscopic data evaluation in a structured way. It is a reading application supporting convenient reading of MR Single Voxel Spectroscopy (SVS) data and MR Chemical Shift Imaging (CSI) data of body regions which have been acquired for in-vivo examinations of the cell metabolism of tissue and organs.

The medical device *syngo*.MR Spectroscopy comprises *syngo*.MR Spectro SVS, *syngo*.MR Spectro CSI and *syngo*.MR Spectro Extension.

- ***syngo*.MR Spectro SVS:** provides evaluation of MR Single Voxel Spectroscopy (SVS) data with comprehensive workflow guidance.
- ***syngo*.MR Spectro CSI:** provides evaluation of MR Chemical Shift Imaging (CSI) data with comprehensive workflow guidance. *syngo*.MR Spectro CSI includes the possibility of an integrated reading of MR images and CSI spectroscopy data for prostate exams.
- ***syngo*.MR Spectro Extension:** provides access to advanced parameters, which allow the advanced user to configure the post processing and display of spectro results according to his / her personal needs. Both Single Voxel Spectroscopy (SVS) and Chemical Shift Imaging (CSI) data are supported.

syngo.MR Spectro Engine bundles the above three packages for post-processing for purchase separately or as part of the *syngo*.MR Spectro Engine.

5. Intended Use

syngo.MR Spectroscopy is a post-processing application to analyze and evaluate MR spectroscopy data. It provides evaluation of MR Single Voxel Spectroscopy (SVS) data and MR Chemical Shift Imaging (CSI) data with workflow guidance to support the diagnostic process.

syngo.MR Spectroscopy includes the possibility of an integrated reading of MR images and spectroscopy data for spectroscopy exams and focuses on ease-of-

use by reducing complexity. A novel fit-algorithm reduces the need for manual data processing and offers the user reproducible evaluation results. When interpreted by a trained physician, these results provide information that may assist in diagnosis.

The post-processing tool fits and displays spectra and provides intuitive representations of the metabolic profile. The calculation and display of predefined results such as spectra, spectral maps, and metabolite images is provided. The evaluation can be adapted by the customer via protocol modification and task configurations. Interactive reading of spectroscopy exams is supported by side-by-side display of MR images and spectroscopy results, and synchronized display.

6. Substantial Equivalence

syngo.MR Spectroscopy offers reading / viewing and reporting functionality. These functionalities are based on the basic functionality already cleared for *syngo*.via and adapted for *syngo*.MR Spectroscopy. The *syngo*.MR Spectroscopy software has been found to be substantially equivalent to the following current legally marketed devices (please refer to Table 1):

Table 1: Predicate devices for *syngo*.MR Spectroscopy

Predicate Device Name	FDA Clearance Number	FDA Clearance Date
MAGNETOM Aera, MAGNETOM Skyra with software *syngo* MR D11A	K101347	October 01, 2010
syngo.x®[3]	K092519	August 27, 2009

7. Summary of Technological Characteristics of the Principal Device as Compared With the Predicate Device

syngo.MR Spectroscopy is aimed at increasing ease of use by simplifying workflows and features and reduces complexity from the user's perspective through an improved algorithm and intuitive processing capabilities. It offers additional spectroscopy specific features based on the currently cleared *syngo*.x and improved features based on the currently cleared *syngo* MR D11A (on MAGNETOM Aera and MAGNETOM Skyra).

New features of *syngo*.MR Spectroscopy that are not part of the *syngo* MR D11A (on MAGNETOM Aera and MAGNETOM Skyra) are related to workflow support, data processing, quality assessment of the spectra, and configuration of MR spectroscopy parameters.

[3] *syngo*.x® is a registered trademark of Siemens AG.

8. General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. These potential hazards are controlled via software development, verification and validation testing. To minimize hazards, Siemens adheres to recognized and established industry practices and standards. Furthermore the operators are health care professionals familiar with and responsible for the evaluating and post processing of magnetic resonance images.

syngo.MR Spectroscopy conforms to the applicable FDA recognized and international IEC, ISO, and NEMA standards with regards to performance and safety as required by the respective MR FDA Guidance Document.

9. Conclusion as to Substantial Equivalence

syngo.MR Spectroscopy is intended for similar indications as cleared in the predicate software noted. In summary, Siemens is of the opinion that *syngo*.MR Spectroscopy does not raise new questions of safety or effectiveness and is substantially equivalent to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Nadia Sookdeo
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51 Valley Stream Parkway
MALVERN PA 19355

APR 13 2012

Re: K120315
Trade/Device Name: *syngo*.MR Spectroscopy
Regulation Number: CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 30, 2012
Received: February 1, 2012

Dear Ms. Sookdeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120315

Indications for Use Statement

510(k) Number (if known) _____

Device Name: ***syngo*.MR Spectroscopy**

Indications for Use:
syngo.MR Spectroscopy is a post-processing application to analyze and evaluate MR spectroscopy data. It provides evaluation of MR Single Voxel Spectroscopy (SVS) data and MR Chemical Shift Imaging (CSI) data with workflow guidance to support the diagnostic process.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OVID)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation
and Safety

510(k) K120315